

REMARKS

This paper is being presented in response to the final official action dated March 19, 2009, wherein claims 1-3, 7, 10, and 11 are pending and have been rejected under 35 USC § 103(a) as being obvious over International Publication No. WO 00/61200 (Patel) in view of U.S. Patent No. 5,441,561 (Chujo et al.). This paper also is being presented in accordance with 37 CFR § 1.116(e) in an effort to place the application in condition for allowance. The arguments presented herein were not (and could not have been) presented in prior communications to the U.S. Patent and Trademark Office (Patent Office) due to the applicants' good faith belief that all prior rejections had been overcome by amendment and/or argument. Reconsideration and withdrawal of the rejection are respectfully requested in view of the following remarks.

I. Proper Basis for a 35 USC § 103(a) Rejection

A determination that a claimed invention is obvious under § 103(a) is a legal conclusion involving four factual inquiries: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). Obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the claimed subject matter pertains, who is presumed to have all prior art references in the field of the invention available to him/her. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Furthermore, obviousness must be determined as of the time the invention was made and in view of the state of the art that existed at that time. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050-51 (Fed. Cir. 1988).

The Patent Office "has the burden under § 103 to establish a prima facie case of obviousness." *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988); MPEP § 2142 (8th Ed., Rev. 6, Sept. 2007) ("The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness."). The Supreme Court recently identified a number of rationales that may be used to support a conclusion of obviousness, consistent with the framework set forth in its decision in *Graham v. John Deere. Co.* See *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1739-40 (2007). These and other representative rationales are described at MPEP § 2143 (8th Ed., Rev. 6, Sept. 2007). Regardless of the supporting rationale, however, the Patent Office must clearly articulate facts and reasons why the claimed invention "as a whole" would have been obvious to a hypothetical person having ordinary skill in the art at least as of the claimed invention's effective filing date. See *KSR Int'l*, 127 S.Ct. at 1741 (citing with approval *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there

must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”)); see *also* MPEP § 2143 (“The key to supporting any rejection under 35 USC § 103 is the clear articulation of reason(s) why the claimed invention would have been obvious.”).

II. The 35 USC § 103(a) Rejection Is Respectfully Traversed

A. The Action Does Not Set Forth A Prima Facie Case of Obviousness

The action does not clearly articulate facts and reasons why the claimed invention as a whole would have been obvious to a hypothetical person having ordinary skill in the art. Specifically, the action does not articulate accurate findings of fact relating to the scope and content of the prior art, and the differences between the claimed invention and the prior art. Still further, while the action appears to rationalize its conclusion of obviousness, the action does not articulate facts sufficient to support the asserted rationale. See MPEP § 2143. The action, therefore, does not set forth a prima facie case of obviousness. Accordingly, the applicants respectfully traverse the rejection, and request reconsideration and withdrawal of the rejection.

Independent claim 1 recites a plasma-sterilization indicator that includes: (a) at least one compound selected from the group consisting of adsorption indicators and metal chelate-titration indicators; (b) at least one organic metal compound; and, (c) a polyvalent alcohol. Each of dependent claims 2, 3, and 7 recites additional features of the three components. Independent claim 10 recites a sterilization packaging material, a part of which is made of a gas permeable paper or non-woven fabric. The packaging material has an indicator area of the same indicator recited in claim 1. Dependent claim 11 mirrors dependent claim 2, both of which further define the adsorption indicators and metal chelate-titration indicators.

The primary prior art—Patel—states:

Any chemical which produces reactive species with a plasma or hydrogen peroxide which, when reacted with a indicator compound, degrade, cleave or add to the molecule or react to form a colored compound can be used as an indicator activator. Similarly, a chemical which when reacted with plasma or hydrogen peroxide and produces a chemical which changes environment, e. g., pH of the medium, can also be used as an indicator activator. Production of an acid or base introduces a change of a pH-sensitive dye. A variety of classes of organic and inorganic compounds may be used as activators for monitoring hydrogen peroxide and its plasma. They include alcohols, amides, amines, bisulfites, bisulfates, carbonates, carbamates, chelates, metal complexes, cyanates, esters, halides, halocarbons, ketones, nitrites, nitrates, nitriles, nitro, nitroso, oximes, phenols, phosphates, sulfates, sulfides, sulfites, thiocyanates, ureas, urethanes, salts, oxidants and reducing agents. Organic and inorganic salts, especially halides were very effective activators.

Patel at page 12, lines 10-24. The applicants respectfully submit, however, that Patel does not disclose what kinds of alcohols fall within the range of that which is described as the indicator activator. Furthermore, the foregoing description specifies that the metal complexes

and alcohols are alternative examples of the indicator activator of Patel. Still further, the effective activators of Patel are organic and inorganic salts, especially halides, and metal complexes and alcohols are examples of generally-cited activators, which are not so effective. The combination of the an organic metal complex and an alcohol—as recited in each of the pending, rejected claims—is neither taught nor suggested in Patel.

Chujo discloses that the ink-jet recording ink thereof “is known in basic ingredients themselves, and comprises water, a water-soluble organic solvent and a color material as essential ingredients,” and that preferred examples of the water-soluble organic solvents include polyhydric alcohols. Chujo further describe that, as the amount of the water-soluble organic solvent increases, the ink has an increased viscosity and reduced output stability. See Chujo at col. 3, lines 35-60. Chujo, thus, merely teaches that polyhydric alcohols are preferable as an organic solvent used in combination with water, and that these alcohols influence the viscosity of the ink composition. Chujo, however, discloses neither a plasma-sterilization indicator nor a sterilization packaging material capable of containing an article to be sterilized by plasma sterilization treatment employing the indicator. The problem to be solved by Chujo is to obtain highly precise images without generating image defects, such as blank areas, fluctuations in dot diameter, or disturbed dot shapes. See Chujo’s summary of invention.

The pending claims recite the presence of a specific alcohol—a polyvalent alcohol. That alcohol is used to increase the discoloration speed of the indicator. See the fourth full paragraph at page 9 of the specification. In contrast, the alcohols in Patel are merely taught as one example among several general additives. Consequently, and because Chujo and Patel seek to solve different problems, a person having ordinary skill in the art would have no apparent reason to combine Chujo with Patel to arrive at the claimed invention. Furthermore, neither Chujo nor Patel contains disclosure or teachings that would compel the skilled artisan to make the combination suggested in the action. Still further, even if the teachings were combined, the combination would not result in the claimed invention—an invention that uses a specific combination of an organic metal complex with a polyhydric alcohol in a plasma-sterilization indicator—because the metal complexes and alcohols of Patel are listed as examples of generally-cited activators serving as alternatives to each other.

B. Evidence of Unexpected Results Is Present in the Specification

Once the Patent Office properly sets forth a *prima facie* case of obviousness, the burden shifts to the applicants to come forward with evidence and/or argument supporting patentability. See *In re Glaug*, 283 F.3d 1335, 1338 (Fed. Cir. 2002). Rebuttal evidence is “merely a showing of facts supporting the opposite conclusion.” *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). Evidence rebutting a *prima facie* case of obviousness can

include evidence of unexpected results. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 1369 (Fed. Cir. 2007). The Patent Office must always consider such evidence supporting patentability. See, e.g., *In re Sullivan*, 498 F.3d 1345, 1352-53 (Fed. Cir. 2007) (reversing a Patent Office decision of obviousness because the Patent Office failed to consider the applicants' evidence rebutting a prima facie case of obviousness). If the Patent Office determines that such evidence is not compelling or is insufficient, then the Patent Office should specifically set forth the facts and reasoning supporting that determination. MPEP § 2145 (8th Ed., Rev. 6, Sept. 2007).

Even if, somehow, the combination of Patel and Chujo could render the claimed invention obvious, the applicants' specification provides evidence of unexpected effects of the specific combination of an organic metal complex with a polyhydric alcohol in a plasma-sterilization indicator. Compare Examples 1 and 2 with Comparative Examples 1 and 2 of the application at pp. 15-23. That evidence sufficiently rebuts the action's contention that the combination of Patel and Chujo renders the pending claims prima facie obvious.

C. Conclusion

In view of the foregoing, the applicants respectfully traverse the § 103(a) rejection, and respectfully submit that the claimed invention is patentable under all criteria relevant to a determination of unobviousness. The applicants, therefore, respectfully request reconsideration and withdrawal of the rejection, and allowance of all pending claims.

Prima facie obviousness under § 103 is a legal conclusion—not a fact—based on underlying facts. *In re Rinehart*, 531 F.2d 1048, 1052 (CCPA 1976); *In re Kumar*, 418 F.3d 1361, 1365 (Fed. Cir. 2005) ("Determination of obviousness under 35 USC § 103 is a legal conclusion based on underlying facts."). The foregoing response identifies facts (e.g., evidence in the form of statements in the prior art) rebutting the alleged legal conclusion that the claimed invention is prima facie obvious. Indeed, to the extent that a prima facie case of obviousness has been made or even exists, the foregoing response identifies facts (e.g., evidence in the form of comparative data) that rebut a legal conclusion that the claimed invention is prima facie obvious. All of these facts must be evaluated along with the facts on which the legal conclusion was originally reached—not the legal conclusion itself. Having requested herein reconsideration of the legal conclusion set forth in the official action, the Patent Office is obligated to address all of the evidence and base its forthcoming legal conclusion(s) on such evidence, uninfluenced by its earlier conclusions. *Rinehart*, 531 F.2d at 1052.

Should the examiner wish to discuss the foregoing, or any matter of form or procedure in an effort to advance this application to allowance, the examiner is urged to contact the undersigned attorney.

Respectfully submitted,

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